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의학석사 학위논문

**Effect of vibratory positive  
expiratory pressure on  
pulmonary function after lung  
resection surgery: a randomized  
trial**

**진동형 양압호기의 사용이 폐절제술  
후 폐기능에 미치는 영향**

2013 년 8 월

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# Abstract

**Background:** There are limited data whether vibratory positive expiratory pressure improves postoperative pulmonary function recovery in patients undergoing pulmonary resection surgery.

**Methods:** We randomly assigned 49 patients undergoing video-assisted thoracoscopic pulmonary resection surgery to use either vibratory positive expiratory pressure using Acapella® device as well as incentive spirometry (the Acapella group) or incentive spirometry alone (the control group) postoperatively. Primary end point was forced expiratory volume in 1 second (FEV1, percentage of reference value: FEV1 %) on the third postoperative day. Analyses were performed on an intention-to-treat basis.

**Results:** There was no significant between-group difference in the primary end point, which was  $58.88 \pm 16.39\%$  in the Acapella group and  $55.43 \pm 18.71\%$  in the control group ( $P=0.427$ ). Patients in the Acapella group had significantly longer postoperative length of stay ( $5.6 \pm 2.2$  vs.  $4.4 \pm 1.6$  days,  $P=0.038$ ).

**Conclusions:** The use of vibratory positive expiratory pressure using Acapella device had no significant improvement in postoperative pulmonary function in patients undergoing pulmonary resection surgery. Patients who used the Acapella device in the early postoperative period within three days showed significant longer postoperative hospital length of stay. (ClinicalTrials.gov number, NCT01826136.)

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**Keywords:** Acapella, vibratory positive expiratory pressure, lung resection surgery, pulmonary function

**Student Number:** 2011-23759

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# Introduction

Airway clearance is the main concern in the postoperative care for patients undergoing pulmonary resection surgery. Failure to clear secretions from the respiratory tract after lung operation can cause obstructed bronchopulmonary tree, atelectasis, pneumonia, and potentially life-threatening morbidity and mortality (1). Manual percussion and vibration of the chest wall is a widely used method of respiratory physiotherapy to assist airway clearance. However, it is labor-intensive, operator-dependent, and time-consuming for both hospitalized and in-hospitalized person, and can be painful for patients in the immediate postoperative period of thoracic surgery.

There are various alternatives to facilitate airway clearance and improve pulmonary function. The Acapella® (acapella® DH Green, Smiths Medical ASD. Inc., Keene, NH, USA) is a small hand-held device, which combines high-frequency vibration and positive expiratory pressure thus enhance the clearance of airway secretions and prevent atelectasis (2-5). It has been reported that the use of the Acapella device increased the amount of sputum expectoration in patients with bronchiectasis (3, 4), and the users preferred the Acapella device to conventional method of respiratory physiotherapy (3,



4, 6). It has been emerged as an accepted alternative therapeutic method that clears the airway secretions and increases patients' compliance by motivating themselves to apply therapy. However, few clinical trials have investigated the efficacy of the Acapella device in patients undergoing pulmonary resection surgery. In this study, we hypothesized that vibratory positive expiratory pressure with the use of the Acapella device would enhance the lung function in patients undergoing pulmonary resection surgery in the early postoperative period.

# Methods

## Study Design

We conducted a prospective, single-blinded, randomized trial of Acapella device along with incentive spirometry, compared to conventional treatment using incentive spirometry alone between January and May 2013. The study was conducted in accordance with the Declaration of Helsinki and was approved by Seoul National University Hospital's institutional review board. All patients undergoing lung resection surgery were screened for eligibility daily prior to scheduled surgery by investigators and gave written informed consent before enrollment.

## Patient selection and randomization

Patients between 20 and 65 years old who were scheduled for elective video-assisted thoracoscopic pulmonary resection surgery under suspicion of lung cancer were screened for eligibility. The exclusion criteria were body mass index of less than  $15 \text{ kg/m}^2$  or more than  $30 \text{ kg/m}^2$ , history of respiratory tract infection within 3 months, emergency surgery, previous or ongoing treatment with supplemental oxygen, intubated state or under mechanical ventilator support

preoperatively, baseline partial pressure of arterial oxygen ( $\text{PaO}_2$ ) of less than 70 mmHg or partial pressure of arterial carbon dioxide ( $\text{PaCO}_2$ ) of more than 50 mmHg, baseline forced expiratory volume in 1 second (FEV1) of less than 30% of predicted value, unconsciousness, neuromuscular disease, and any other physical or psychological condition not feasible to use vibratory positive expiratory pressure. After being screened and excluded by criteria, patients who extubated at the end of the surgery and admitted to the intensive care unit (ICU) with intravenous patient-controlled analgesics (PCA) were ultimately enrolled to the trial. Block randomization was conducted using automated computer randomization system performed by a clinician not involved in this study.

Each patient included in this trial underwent baseline pulmonary function test measuring FEV1 and forced vital capacity (FVC), and arterial blood gas analysis preoperatively. All measures of FEV1 and FVC were expressed as a percentage of the predicted value.

## Acapella

Acapella consists of a counterweighted plug and metal strip attached to a lever, and a magnet. Airflow oscillation is created by breaking and reforming of a magnetic attraction by the plug as it intermittently

occludes air passing through the device (6). The device includes two types: a blue one for patients who cannot maintain their expiratory flow above 15 L/min for over 3 seconds, and a green one for patients who can maintain expiratory flow above or equal to 15 L/min for at least 3 seconds (5, 7). We used the green one in this trial as we excluded the patients with impaired preoperative pulmonary function (Figure 1).

For appropriate use of the Acapella device, patients were instructed to inhale deeply and hold their breaths for 2 to 3 seconds. The components of Acapella treatment included 10 active slow exhalations causing oscillation through the device followed by active coughs in a set cycle repeated at least every two hours while awake. The patients were allowed to control a dial on the bottom of the device to set expiratory resistance as their convenience.

## Incentive spirometry

Incentive spirometry is designed to take a deep breath mimicking spontaneous yawning or sighing (5). The device supports increasing or maintaining inhaled lung volume, improves sputum expectoration, and avoids serious lung infection, especially after surgery (8). Patients were encouraged to use the incentive spirometry every two hours in tolerable sitting position, taking ten deep inhalations each set with their

lips sealed around the mouthpiece and motivated by visual feedback of balls in the device rising with active inhalation.

## Study treatments

Patients in the Acapella group were treated with both the Acapella device and the incentive spirometry (HS-IM-1200, Hyupsung Medical Co. LTD., Yangju, Korea) (Figure 2) alternatively. At the time of ICU admission and randomization, patients in the Acapella group were provided with the Acapella devices and were instructed how to use them. Patients in the control group were treated only with the incentive spirometry, the routine postoperative lung care device in our institute. Patients in both groups were encouraged to perform the devices at least every two hours while awake.

## Outcomes

The primary end point was FEV1 on the third postoperative day. Secondary outcomes included FVC, ratio of  $\text{PaO}_2$  to the fraction of inspired oxygen ( $\text{FIO}_2$ ), pain score, morphine requirement to alleviate pain, comfort score, hemodynamic data, amount of drainage via chest tube, hospital length of stay, and any adverse event.

### **Pulmonary function test**

FEV1 and FVC were measured by a portable spirometer (MS01, Micro Medical Ltd., Kent, UK) preoperatively, immediately after the surgery, at six hours after surgery, and on the first, second, and third postoperative day. Immediate postoperative values were evaluated an hour after surgery. Patients were instructed how to blow through the spirometer and the best value among three consecutive measurements was recorded for analysis. Individual mouthpiece for spirometer was used for each patient. The portable spirometer machine was disinfected regularly, and patients with respiratory tract infection were excluded from the study in the patient-screening step.

### **Oxygenation**

A ratio of PaO<sub>2</sub> to FIO<sub>2</sub> was measured before the surgery, immediately after the surgery, at six hours after surgery, and on the first postoperative day. We applied a Venturi mask (MM061, MOW Medical, Wonju, Korea) to obtain an accurate FIO<sub>2</sub> for PaO<sub>2</sub>:FIO<sub>2</sub> ratio measurement at least 30 minutes prior to each arterial sampling for blood gas analysis. Room air's FIO<sub>2</sub> was assumed to be 0.21. FIO<sub>2</sub> in the range of 0.35 to 0.5 was delivered to the patients to maintain acceptable peripheral saturation via pulse oximetry. All arterial blood

samplings were performed through the pre-placed intraoperative arterial cannula to minimize invasive procedures.

### **Pain score and morphine requirements**

Postoperative pain was evaluated using a visual analog scale on a scale of 0 (free of pain) to 10 (the worst pain that can be imagined) immediately after the surgery, at six hours after surgery, and on the first, second, and third postoperative day. Immediate postoperative values were evaluated an hour after surgery. Intravenous morphine requirements were measured during the first 3 days after the surgery. If the patient was administered with other types of opioids, equivalent intravenous morphine dose was calculated. The amount of drug infused through the intravenous PCA was also converted and added to equivalent morphine dosage.

### **Comfort score and preference**

Patient comfort was assessed with a visual analog scale, using a written script delivered by the previous investigators (9), to demonstrate the patient's comfort response as follows: 1 = comfortable with treatment; 2 = uncomfortable with treatment, but able to tolerate treatment; 3 = painful, more uncomfortable, but is willing to continue

treatment; 4 = severe pain, but can tolerate treatment; 5 = intolerable pain. Comfort score was evaluated on the first postoperative day.

### **Safety outcomes**

Blood pressures, heart rate, and peak daily body temperature were recorded at the same time sequence with pulmonary function parameters measurement. The amount of drainage via chest tube during the first 24 hours after surgery was assessed and the duration of the chest tube placement, total hospital length of stay and the postoperative length of hospital stay were recorded. Any adverse events such as chest tube dislodgement, surgical wound dehiscence, hemodynamic instability, cardiac arrhythmia, occurrence of pneumonia, respiratory distress or failure, unplanned intubation or mechanical ventilation, or readmission to ICU were reviewed.

### **Statistical analysis**

All analyses were conducted on an intention-to-treat basis. IBM SPSS Statistics 19.0.0 (SPSS, Chicago, IL) was used for statistical analysis. Continuous data are presented as mean  $\pm$  standard deviation (SD) and were compared with the use of the Mann-Whitney test. Categorical and ordered data are reported as numbers and percentages and were



compared by means of Pearson's chi-square test or Fisher's exact test. FEV1 measured as time sequence was analyzed by means of a repeated-measures analysis of variance. A two-sided P value of less than 0.05 was considered to be statistically significant.



**Figure 1.** Acapella® device.



**Figure 2.** Incentive spirometry device.

# Results

## Patients

Patients were recruited from January through May 2013. Of the 92 patients who were screened for eligibility, 49 (53.3%) were enrolled and were randomly assigned to either vibratory positive expiratory pressure using Acapella device as well as incentive spirometry treatment group (the Acapella group) or incentive spirometry group (the control group) postoperatively (Figure 3). Forty-three patients did not fulfill the inclusion criteria, six patients were excluded because surgical approach was converted to open thoracotomy in the middle of video-assisted thoracoscopic procedure; applying intravenous PCA was rejected by one patient due to previous analgesic-related discomfort; epidural PCA was given to one patient; multiple lesions involving three lobes were resected during operation in one patient; other procedure (excision of left atrial myxoma) was added in one patient; thirty-three (35.9%) patients were admitted to postanesthesia care unit (PACU) instead of ICU after completion of surgery.

Baseline characteristics of the patients and operative characteristics are shown in Table 1. The patients in the Acapella group had significantly more frequent history of use of anti-platelet medication

before hospital admission (6 (24.0%) vs. 0 (0.0%),  $P=0.022$ ). Of six patients with history of anti-platelet medication before admission for surgery, three patients had aspirin, one had cilostazole, one had clopidogrel, and the last patient had both aspirin and clopidogrel. The duration of discontinuation of such medication varied from 2 to 18 days before the operation. The mean operation time as well as mean anesthesia time were significantly longer in the Acapella group ( $160\pm45.0$  vs.  $117\pm37.3$  min and  $218\pm47.6$  vs.  $174\pm41.5$  min,  $P=0.001$  and  $0.002$ , respectively). Other patient characteristics or operative data were not different between the two groups.

## Pulmonary function

Perioperative pulmonary function measures are presented in Table 2. There was no significant difference in baseline FEV1 and FVC of two groups. The mean FEV1 on the third postoperative day was  $58.88\pm16.39\%$  in the Acapella group and  $55.43\pm18.71\%$  in the control group, and the difference between the two treatment groups was not significant ( $P=0.427$ ). The mean difference of FEV1 on the third postoperative day from the baseline preoperative value was  $35.30\pm15.34\%$  in the Acapella group and  $43.70 \pm 14.23\%$  in the control group. The amount of decrease in FEV1 on the third postoperative day

from the baseline was lower in the Acapella group than in the control group, however, the difference was not statistically significant ( $P=0.085$ ). FVC on the third postoperative day ( $48.30\pm14.49\%$  vs.  $45.55\pm16.20\%$ ) or the difference of FVC on the third postoperative day from the baseline value ( $35.66\pm16.55\%$  vs.  $39.02\pm13.82\%$ ) did not differ between the groups ( $P=0.474$  and  $0.268$ , respectively). Figure 4 shows the sequential change of FEV1 in the two groups at baseline and during the follow-up period. There was no significant difference between the two groups ( $P=0.965$ ).

## Oxygenation

Preoperative PaO<sub>2</sub>:FIO<sub>2</sub> ratio was similar in the two groups (Table 2). PaO<sub>2</sub>:FIO<sub>2</sub> ratio on the first postoperative day was  $391.86\pm77.47$  in the Acapella group and  $356.35\pm80.98$  in the control group. The patients in the Acapella group showed higher PaO<sub>2</sub>:FIO<sub>2</sub> ratio a day after surgery than in the control group with no statistical significance ( $P=0.118$ ).

## Postoperative pain and patient comfort

Table 3 shows a comparison of pain, morphine requirements, comfort score, and patients' preference over devices treated between the

groups. There was no significant difference in postoperative pain, or in the mean amount of morphine consumption for three days after the surgery ( $P>0.05$ ). Patients showed more comfort with the treatment device when they were in use of the Acapella device in addition to the incentive spirometry than in use of only incentive spirometry ( $P<0.001$ ). Twenty-three of twenty-five (92.0%) patients in the Acapella group who used both devices at the same period preferred the Acapella device to the incentive spirometry for postoperative respiratory physiotherapy treatment ( $P<0.001$ ).

## Safety

Hemodynamic data, including blood pressure, heart rate, and peak daily body temperature, were similar in the two groups except peak body temperature on the first postoperative day (Table 4). No hemodynamic instability was found during the follow-up period in either group. The mean amount of the drainage via chest tube during the first 24 hours after surgery was significantly higher in the Acapella group ( $385.1\pm159.8$  vs.  $285.2\pm117.6$  mL,  $P=0.011$ ) (Table 5). A duration of placement of chest tube and postoperative hospital length of stay were all significantly longer in the Acapella group ( $5.4\pm2.1$  vs.  $4.2\pm1.0$  days and  $5.6\pm2.2$  vs.  $4.4\pm1.6$  days,  $P=0.016$  and  $0.038$ , respectively). Blood

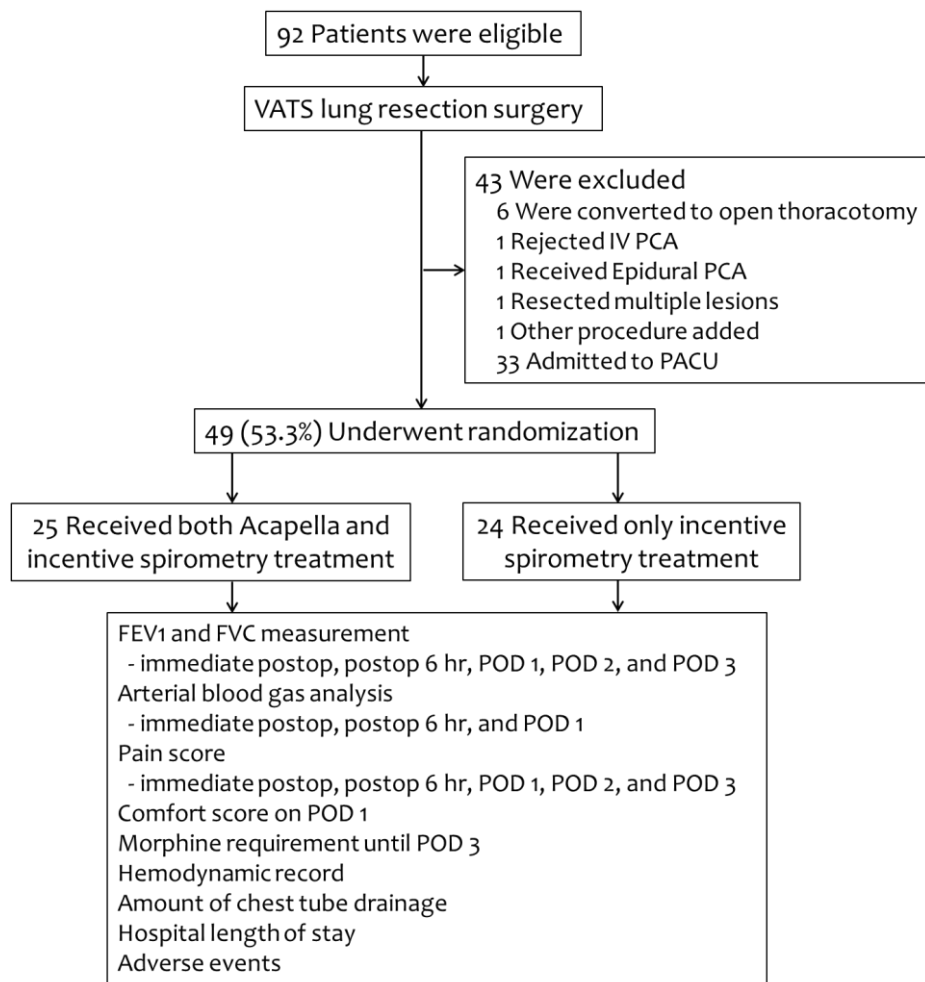
product transfusion was performed in two of twenty-five (8.0%) patients in the Acapella group whereas none of twenty-four patients in the control group was transfused. The difference of transfusion frequency was not statistically significant ( $P=0.490$ ). No significant adverse events were observed in either group.

## Subgroup analysis

We performed subgroup analysis with lobectomy cases for data homogeneity (Table 6). Baseline patient characteristics and operative clinical data were well balanced between the two groups. History of use of anti-platelet medication was more frequent in the Acapella group (4 vs. 0), but the difference was not statistically significant ( $P=0.105$ ). Total operation time and anesthesia time were longer in the Acapella group than in the control group ( $158\pm53.9$  vs.  $131\pm31.9$  min and  $216\pm52.8$  vs.  $188\pm35.7$  min), but the differences were not significant ( $P=0.112$  and  $0.104$ , respectively). Preoperative pulmonary function and oxygenation parameters were similar in the two groups. FEV1 on the third postoperative day was  $57.94\pm14.22\%$  in the Acapella group and  $53.92\pm17.15\%$  in the control group ( $P=0.352$ ). Difference of FEV1 on the third postoperative day from the preoperative value and  $\text{PaO}_2:\text{FIO}_2$  ratio on the first postoperative day



did not differ between the groups ( $34.97 \pm 15.96\%$  vs.  $45.66 \pm 12.34\%$  and  $388.56 \pm 87.34$  vs.  $349.21 \pm 84.88$ ,  $P=0.084$  and  $0.158$ , respectively). Amount of drainage via chest tube during the first 24 hours after surgery was higher in the Acapella group than in the control group without statistical significance ( $379.3 \pm 163.0$  vs.  $305.5 \pm 120.7$  mL,  $P=0.088$ ). However, the duration of chest tube placement was significantly longer in the Acapella group ( $5.6 \pm 2.1$  vs.  $4.3 \pm 1.1$  days,  $P=0.048$ ) whereas postoperative length of stay was not significantly different ( $5.8 \pm 2.2$  vs.  $4.7 \pm 1.8$  days,  $P=0.085$ ). Patients in the Acapella group showed more comfort with treatment than in the control group ( $P<0.001$ ).



**Figure 3.** Screening, Randomization, and Follow-up.

PCA denotes patient-controlled analgesia, PACU postanesthesia care unit, ICU intensive care unit, FEV1 forced expiratory volume in 1 second, FVC forced vital capacity, and POD postoperative day.

**Table 1.** Baseline Characteristics of the Patients and Operative Characteristics\*

Characteristics	Acapella (n=25)	Control (n=24)	P value
Male/Female	14 (56.0)/11 (44.0)	12 (50.0)/12 (50.0)	0.778
Age	54±10.4	55±8.3	0.651
Body mass index†	23.5±2.46	23.2±3.23	0.659
Never/current/ex-smoker	15 (60.0)/7 (28.0)/3 (12.0)	13 (54.2)/3 (12.5)/8 (33.3)	0.140
ASA Class I/II	8 (32.0)/17 (68.0)	15 (62.5)/9 (37.5)	0.046
Hypertension	11 (44.0)	4 (16.7)	0.062
DM	5 (20.0)	2 (8.3)	0.417
Stroke	1 (4.0)	0 (0.0)	1.000
Ischemic heart disease	1 (4.0)	1 (4.2)	1.000
Arrhythmia	0	0	
COPD	0 (0.0)	1 (4.2)	0.490
Asthma	1 (4.0)	0 (0.0)	1.000
History of previous pulmonary Tb	4 (16.0)	3 (12.5)	1.000
Previous anti-platelet medication‡	6 (24.0)	0 (0.0)	0.022
History of previous operation			0.769
Never	10 (40.0)	8 (33.3)	
Pulmonary operation	0 (0.0)	1 (5.3)	
Non-pulmonary operation	15 (60.0)	15 (62.5)	
Pathology			0.125
Adenocarcinoma	21 (84.0)	12 (50.0)	
Bronchioloalveolar carcinoma	1 (4.0)	3 (12.5)	
Squamous cell carcinoma	1 (4.0)	4 (16.7)	
Metastasis	1 (4.0)	4 (16.7)	
Benign	1 (4.0)	1 (4.2)	
Extent of operation			0.214
Lobectomy	21 (84.0)	16 (66.7)	
Segmentectomy	3 (12.0)	2 (8.3)	
Wedge resection	0 (0.0)	3 (12.5)	
Metastasectomy	1 (4.0)	3 (12.5)	
Operation time (min)	160±45.0	117±37.3	0.001
Anesthesia time (min)	218±47.6	174±41.5	0.002

\* Data are means ±SD or number (percent). There were no significant differences between the two study groups in any of the baseline characteristics listed above, with the exception of the distribution of

ASA class, for which  $P=0.046$ , and the history of previous antiplatelet medication, for which  $P=0.022$ .

† The body mass index is the weight in kilograms divided by the square of the height in meters.

‡ The drugs medicated were aspirin for three patient, cilostazol for one patient, clopidogrel for one patient, and both aspirin and clopidogrel for one patient.

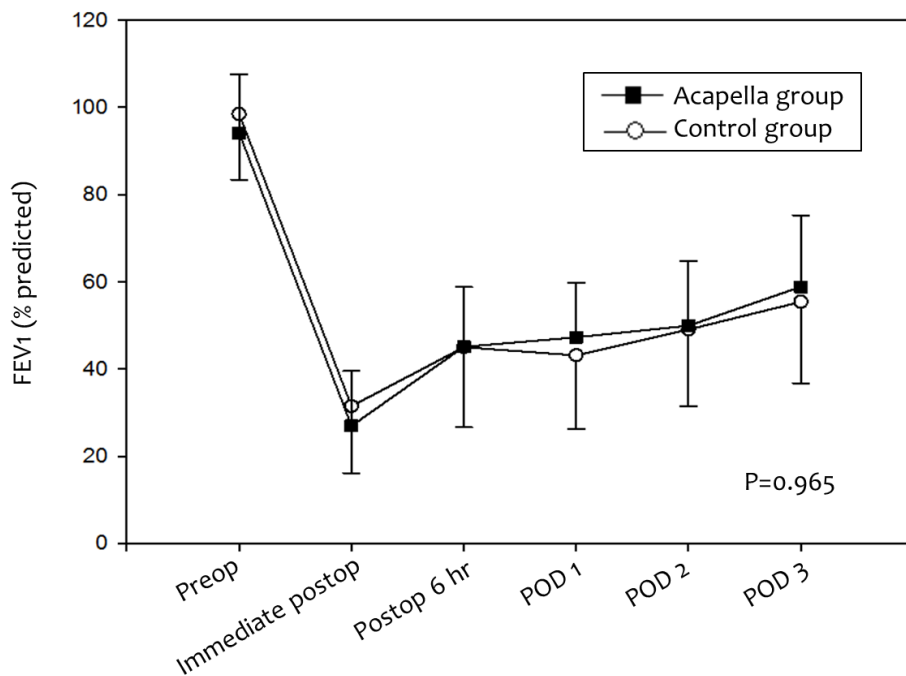
**Table 2.** Comparison of Perioperative Pulmonary Function and Oxygenation\*

Parameters		Acapella (n=25)	Control (n=24)	P value
FEV1 (% predicted)†	Preoperative	94.19±13.38	98.47±15.04	0.358
	Immediate postop	26.94±12.58	31.49±15.36	0.122
	Postop 6 hr	45.08±13.74	44.99±18.38	0.388
	POD1	47.26±12.58	43.12±16.94	0.316
	POD2	49.95±14.89	49.07±17.62	0.886
	POD3	58.88±16.39	55.43±18.71	0.427
	Change on POD3	35.30±15.34	43.70±14.23	0.085
FVC (% predicted)†	Preoperative	83.96±12.36	84.10±14.39	0.976
	Immediate postop	24.05±12.49	26.40±12.89	0.192
	Postop 6 hr	38.50±12.02	36.57±15.04	0.213
	POD1	37.30±10.41	33.80±13.03	0.192
	POD2	41.35±14.69	39.76±13.78	0.599
	POD3	48.30±14.49	45.55±16.20	0.474
	Change on POD3	35.66±16.55	39.02±13.82	0.268
PaO <sub>2</sub> :FIO <sub>2</sub> ratio‡	Preoperative	505.79±83.47	475.09±37.93	0.260
	Immediate postop	279.03±91.79	250.03±84.72	0.281
	Postop 6 hr	374.06±67.46	376.15±82.17	0.964
	POD1	391.86±77.47	356.35±80.98	0.118

\* Data are means ±SD. There were no significant differences between the two groups. Immediate postoperative values were evaluated 1 hour after surgery. The change on POD3 was calculated by preoperative value minus POD3 value. FEV1 denotes forced expiratory volume in 1 second, FVC forced vital capacity, and POD postoperative day.

† FEV1 and FVC on the third postoperative day were missing for one patient in the control group.

‡ Preoperative  $\text{PaO}_2\text{:FIO}_2$  ratio was missing for one patient in the control group,  $\text{PaO}_2\text{:FIO}_2$  ratios on the first postoperative day were missing for three patients in the control group and for two patients in the Acapella group.



**Figure 4.** Comparison of FEV1 Change.

FEV1 (% predicted) measured in the two groups at baseline and during follow-up are shown. FEV1 denotes forced expiratory volume in 1 second, and POD postoperative day. P value for the comparison of FEV1 between groups is from a repeated-measures analysis of variance.

**Table 3.** Comparison of Pain Score, Morphine Requirements, Comfort, and Preference\*

Characteristics		Acapella (n=25)	Control (n=24)	P value
Pain†	Immediate postop	7.4±1.6	6.8±2.1	0.408
	Postop 6 hr	5.0±2.5	5.0±2.7	0.914
	POD1	4.4±2.7	4.7±1.9	0.714
	POD2	4.0±1.9	3.6±1.5	0.473
	POD3	3.8±2.1	2.9±1.3	0.132
Morphine requirement (mg)‡		171.50±82.60	151.10±66.95	0.424
Comfort score§		1.1±0.3	2.9±0.7	<0.001
Preference				<0.001
Acapella		23 (92.0)		
Incentive spirometry		0 (0.0)		
Same		2 (8.0)		

\* Data are means ±SD or number (percent). Immediate postoperative values were evaluated 1 hour after surgery. The patients in the Acapella group expressed more comfort and preferred the Acapella device significantly (both  $P<0.001$ ).

† Pain scores were measured by means of visual analog scale ranging from 0 (free of pain) to 10 (the worst pain can be imagined).

‡ Intravenous morphine requirements were recorded during the first three days after surgery.

§ Patients' comfort was evaluated with scores ranging from 1 to 5 and lower scores indicating more comfort with treatment.



**Table 4.** Hemodynamic Data\*

		Acapella (n=25)	Control (n=24)
Systolic BP (mmHg)	Preoperative	121±13	117±13
	Immediate postop	143±19	143±24
	Postop 6 hr	124±15	125±16
	POD 1	126±12	122±14
	POD 2	116±10	114±9
	POD 3	117±8	115±11
Diastolic BP (mmHg)	Preoperative	72±9	75±10
	Immediate postop	76±11	77±13
	Postop 6 hr	66±11	71±12
	POD 1	67±9	69±10
	POD 2	69±12	73±8
	POD 3	68±10	72±9
Heart rate (beat/min)	Preoperative	71±10	71±11
	Immediate postop	79±14	75±13
	Postop 6 hr	82±14	79±20
	POD 1	79±11	79±12
	POD 2	86±11	84±14
	POD 3	84±12	79±9
Peak body temperature (°C)	Preoperative	36.5±0.4	36.6±0.3
	Immediate postop	36.1±0.5	36.2±0.7
	Postop 6 hr	37.5±0.5	37.4±0.3
	POD 1	37.8±0.4	37.6±0.3
	POD 2	37.5±0.6	37.3±0.5
	POD 3	37.2±0.6	37.1±0.5

\* Data are means ±SD. Immediate postoperative values were recorded 1 hour after surgery. Hemodynamic data were similar in the two groups except peak body temperature on the first postoperative day (P=0.040). POD denotes postoperative day.

**Table 5. Safety Outcomes\***

	Acapella (n=25)	Control (n=24)	P value
Wound dehiscence	0	0	
Chest tube dislodgement	0	0	
Arrhythmia	0	0	
First 24hr drainage (mL)	385.1±159.8	285.2±117.6	0.011
Duration of chest tube (days)	5.4±2.1	4.2±1.0	0.016
Transfusion	2 (8.0)	0 (0.0)	0.490
HLOS (days)	8.2±2.9	7.1±2.2	0.167
Postoperative LOS (days)	5.6±2.2	4.4±1.6	0.038

\* Data are means ± SD or number (percent). The patients in the Acapella group had significantly higher amount of chest tube drainage during the first 24 hours after surgery (P=0.011), significantly longer duration of chest tube placement (P=0.016), and longer postoperative length of stay (P=0.038). HLOS denotes hospital length of stay, and LOS length of stay.

**Table 6.** Comparison of Clinical Data for Lobectomy Cases\*

	Acapella (n=18)	Control (n=16)	P value
Age	55±8.5	56±8.2	0.478
Body mass index†	23.5±2.33	24.0±3.52	0.597
Previous anti-platelet medication‡	4 (22.2)	0 (0.0)	0.105
Operation time (min)	158±53.9	131±31.9	0.112
Anesthesia time (min)	216±52.8	188±35.7	0.104
FEV1 (% predicted)			
Preoperative	92.91±11.14	99.59±15.30	0.241
POD3	57.94±14.22	53.92±17.15	0.352
Change on POD3	34.97±15.96	45.66±12.34	0.084
FVC (% predicted)			
Preoperative	81.04±10.84	85.44±13.72	0.528
POD3	47.06±11.98	44.95±15.29	0.484
Change on POD3	33.98±13.68	40.49±12.78	0.144
PaO <sub>2</sub> :FIO <sub>2</sub> ratio§			
Preoperative	513.47±59.27	469.68±39.58	0.053
POD1	388.56±87.34	349.21±84.88	0.158
Pain¶			
Immediate postop	7.7±1.5	7.2±2.0	0.542
Postop 6 hr	5.4±2.5	5.3±2.9	1.000
POD1	4.7±2.9	5.2±1.7	0.724
POD2	3.7±1.8	3.6±1.5	0.995
POD3	3.9±2.2	3.1±1.4	0.212
Morphine requirement (mg)	168.50±86.45	152.65±70.05	0.827
Comfort score**	1.1±0.2	3.0±0.7	<0.001
First 24hr drainage (mL)	379.3±163.0	305.5±120.7	0.088
Transfusion	0	0	
Duration of chest tube (days)	5.6±2.1	4.3±1.1	0.048
HLOS (days)	8.5±3.0	7.4±2.4	0.221
Postoperative LOS (days)	5.8±2.2	4.7±1.8	0.085

\* Data are means ±SD or number (percent). Immediate postoperative values were evaluated 1 hour after surgery. The patients in the

Acapella group showed significantly longer chest tube placement ( $P=0.048$ ). The patients reported more comfort with the use of both Acapella and incentive spirometry ( $P<0.001$ ). FEV1 denotes forced expiratory volume in 1 second, FVC forced vital capacity, and POD postoperative day.

† The body mass index is the weight in kilograms divided by the square of the height in meters.

‡ The drugs medicated were aspirin for two patients, clopidogrel for one patient, and both aspirin and clopidogrel for one patient.

§ Preoperative  $\text{PaO}_2\text{:FIO}_2$  ratio was missing for one patient in the control group,  $\text{PaO}_2\text{:FIO}_2$  ratios on the first postoperative day were missing for two patients in the control group and for two patients in the Acapella group.

¶ Pain scores were measured by means of visual analog scale ranging from 0 (free of pain) to 10 (the worst pain can be imagined).

|| Intravenous morphine requirements were recorded during the first three days after surgery.

\*\* Patients' comfort was evaluated with scores ranging from 1 to 5 and lower scores indicating more comfort with treatment.

## Discussion

We compared the efficacy of vibratory positive expiratory pressure using Acapella device in addition to the incentive spirometry with the use of incentive spirometry alone as postoperative respiratory physiotherapy in patients undergoing video-assisted thoracoscopic lung resection surgery. We found no significant between-group difference in the primary end point of FEV1 over a period of three postoperative days. Our data shows no additional beneficial effect of vibratory positive expiratory pressure using Acapella device upon incentive spirometry on the pulmonary function parameters after thoracoscopic lung resection surgery in the early postoperative period. This finding of no benefit with respect to lung function is consistent with the results of other previous studies in patients with bronchiectasis (3) or cystic fibrosis (10).

It has been shown that the use of Acapella device increased the amount of sputum expectorated in patients with bronchiectasis (3, 4). We hypothesized that the Acapella device would facilitate airway clearance, hence, improve overall pulmonary function and oxygenation of patients undergoing lung resection surgery in the early postoperative period. We did not obtain the amount of expectorated

sputum directly. Acapella device did not improve postoperative pulmonary function measured with FEV1 and FVC as compared to conventional incentive spirometry use alone.

Patients who used both Acapella device and the incentive spirometry reported that they felt more comfortable with the use of the Acapella device than with the incentive spirometry. Patients preferred the Acapella device to incentive spirometry for postoperative lung care treatment modality. These findings are quite similar to previous studies of Acapella in patients with bronchiectasis as compared to inspiratory muscle trainer (4) or usual airway clearance techniques (3, 6).

More surprising was our finding of potential disadvantage of Acapella usage which increased the amount of chest tube drain during the first 24 hours after surgery and extended postoperative length of stay.

Several mechanisms may contribute to increased amount of chest tube drainage and prolonged postoperative length of hospital stay.

Disproportionate history of use of anti-platelet drug medication and various periods (from 2 to 18 days) of discontinuation of drugs might have affected the drainage via chest tube. However, there was neither significant difference in the event of blood product transfusion nor in any complications related to postoperative bleeding. This finding coincides well with the previous trial in terms of increased chest tube drainage; in that trial, applying of high-frequency chest wall oscillation

to the postoperative patients undergoing pulmonary lobectomy resulted in significantly higher amount of chest drainage during the first 24 hours after surgery (11). Larger amount of chest drainage might contribute to delayed chest tube removal and prolonged postoperative length of stay. Most patients were discharged from hospital a day after the removal of the chest tubes if no other complications were found. Furthermore, greater portion of lobectomy cases in the Acapella group might have affected the postoperative length of hospital stay, because extended range of surgical removal and longer operation time could influence on postoperative recovery time and the restoration of patients' discharge status.

Analysis of the extent of operation showed heterogeneity in distribution of lobectomy, segmentectomy, wedge resection and metastasectomy. There can be different postoperative pulmonary functional loss according to the extent of removed lung parenchyma (12, 13). To minimize this bias we limited our subgroup analysis to only lobectomy cases. The amount of chest tube drainage during the first 24 hours after surgery was insignificantly higher in the patients who used the Acapella, however, the duration of chest tube retainment was still significantly longer in the Acapella group. Postoperative length of stay was not significantly different between the lobectomy cases.

A number of limitations of our study should be noted. The number of recruited patients was too small in this trial to demonstrate the efficacy of the treatment strategy. The paucity of sample size is partly due to short study period and partly because almost a third of the postoperative patients admitted to PACU instead of ICU thus could not be enrolled. Our results raise some concerns about the use of Acapella device in the early postoperative period for patients undergoing pulmonary resection surgery. However, it might help in recovery of pulmonary function after wound site healing or chest tube removal. Furthermore, it might have been helpful in expectorating airway secretions that was not examined in the current trial. Further evaluation is needed about such issues.

In conclusion, this study demonstrates that the Acapella device may offer a user-friendly method but provides no supplemental support for pulmonary function recovery or oxygenation than incentive spirometry use in the early postoperative period after thoracoscopic lung resection surgery. However, applying vibratory positive expiratory pressure in the early postoperative period to the patients undergoing video-assisted thoracoscopic pulmonary resection surgery could increase the amount of drainage via chest tube and prolong the mean duration of chest tube retention and postoperative hospital length of stay. It is reasonable that the Acapella device should be used with caution when



applied in the early postoperative period within three days after lung resection surgery.

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## 초 록

**서론:** 진동형 양압호기의 사용은 폐절제술 환자에서 수술 후 폐기능 회복에 도움이 될 것으로 예상되나 이에 대한 임상적인 연구 결과는 부족하다.

**방법:** 비디오 보조 흉강경술 방법으로 폐절제술이 예정된 49 명의 환자를 대상으로 기존의 유발 폐활량기와 아카펠라 기구를 이용한 진동형 양압호기를 사용하는 군과 유발 폐활량기만을 사용하는 군에 무작위 배정하여 수술 후 3 일째 1 초간 강제호기량을 비교하였다.

**결과:** 수술 후 3 일째 측정된 1 초간 강제호기량은 아카펠라를 사용한 군에서  $58.88 \pm 16.39\%$ , 유발 폐활량기만을 사용한 군에서  $55.43 \pm 18.71\%$ 였다 ( $P=0.427$ ). 아카펠라를 사용한 군에서 수술 후 재원일수는  $5.6 \pm 2.2$  일, 사용하지 않은 군에서는  $4.4 \pm 1.6$  일이었다 ( $P=0.038$ ).

**결론:** 아카펠라 기구를 이용하여 진동형 양압호기를 폐절제술

환자에게 적용했을 때 수술 후 폐기능 회복에 유의한 증가를 가져오지  
않은 반면 수술 후 재원일수가 유의하게 증가하였다.

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**주요어:** 아카펠라, 진동형 양압호기, 폐절제술, 폐기능

**학 번:** 2011-23759